State of Maine
Department of Human Services
11 State House Station
Augusta, Maine
04333-0011

John Elias Baldacci
Governor

John R. Nicholas
Commissioner

TO: Interested Parties

FROM: Christine Zukas-Lessard, Acting Director, Bureau of Medical Services

SUBJECT: Proposed Rule: MaineCare Benefits Manual, Chapter II, Section 80, Pharmacy Services

DATE: June 15, 2004

The Department is proposing prior authorization (PA) requirements for certain MaineCare members over the age of 21 who receive more than 5 brand-name prescriptions per month. The PA requirements will apply to the sixth and subsequent brand-name prescriptions for members residing in certain supervised settings, and when federally approved, those members who are eligible for MaineCare as part of the Non-Categorical Waiver. The proposed prior authorization requirements may exclude those members who are being treated for cancer, HIV, hemophilia, or other conditions. The Department has added a one-time 4-day over ride per calendar year for certain emergency situations. The Department also proposes to provide drug benefit management and/or intensive benefits management for the pharmacy benefit of certain high-cost and/or high utilizing members.

These proposed rules also create the Maine Retail Pharmacy Provider Incentive Payment, which will reward pharmacies providing high quality pharmacy services to MaineCare members in rural areas. The Department will calculate this incentive payment on a quarterly basis, factoring in the pharmacy's rural status, number of unduplicated MaineCare members served, and other specified quality indicators. The Department also proposes to compensate providers dispensing prescriptions to members in nursing facilities, ICFs-MR, and medical and remedial PNMI's a fee of $3.35 when they process certain returned reusable drugs.

The Department has scheduled a public hearing at 9:00 am on July 14, 2004, 442 Civic Center Drive, Augusta, Maine. Anyone in need of special accommodations for any scheduled public hearing should contact the Division of Policy and Provider Services no later than July 9, 2004 at 287-9368 or at 1-800-423-4331 (Deaf/Hard of Hearing).

Rules and related documents may be reviewed and printed form the Bureau of Medical Services website at www.maine.gov/bms/MaineCareBenefitManualRules.htm or, for a fee, interested parties may request a paper copy of rules by contacting Policy and Provider Services at 207-287-9368.

Notice of Agency Rule-making Proposal

AGENCY: Department of Human Services, Bureau of Medical Services

RULE TITLE OR SUBJECT: MaineCare Benefits Manual, Chapter II, Section 80, Pharmacy Services

PROPOSED RULE NUMBER:

CONCISE SUMMARY: These rules propose prior authorization (PA) requirements for certain members receiving more than 5 brand-name prescriptions per month. The PA will apply to the sixth and subsequent brand-name prescriptions for members residing in certain supervised settings, and when federally approved, those members who are eligible for MaineCare as part of the Non-Categorical Waiver. The Department also proposes to provide drug benefit management and/or intensive benefits management for the pharmacy benefit of certain high-cost and/or high utilizing members. The Department has added a one-time 4-day over ride per calendar year for certain emergency situations.

These proposed rules also create the Maine Retail Pharmacy Provider Incentive Payment, which will reward pharmacies providing high quality pharmacy services to MaineCare members in rural areas. The Department also proposes to compensate providers dispensing prescriptions to members in NFs, ICFs-MR, and some PNMIs a $3.35 fee for processing certain returned reusable drugs.

THIS RULE WILL _ WILL NOT X HAVE FISCAL IMPACT ON MUNICIPALITIES.

STATUTORY AUTHORITY: 22 M.R.S.A., § 42, § 3173 , PL 2004, ch. 673.

PUBLIC HEARING: Date: July 14, 2004 9:00 am
Location: Department of Human Services,
442 Civic Center Drive, Augusta, Maine.

Any interested party requiring special arrangements to attend the hearing must contact the agency person listed below before July 9, 2004.

DEADLINE FOR COMMENTS: July 25, 2004

AGENCY CONTACT PERSON: Patricia Dushuttle
AGENCY NAME: Bureau of Medical Services
ADDRESS: 442 Civic Center Drive, 11 State House Station
Augusta, Maine 04333-0011

TELEPHONE: 207-287-9371 FAX 207-287-9369
TTY: 1-800-423-4331 or 207-287-1828 (Deaf or Hard of Hearing)

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

TABLE OF CONTENTS

PAGE

80.01 DEFINITIONS 1

80.01-1 Brand-Name Drug 1
80.01-2 Caloric Supplements/Substitutes 1
80.01-3 Compound Prescription 1
80.01-4 Controlled Substances 1
80.01-5 Covered Drugs 1
80.01-6 DESI 1
80.01-7 Direct Supply Drug List (DSDL) 1
80.01-8 Direct Supply Mail Order Drug List (DSMODL) 1
80.01-9 Direct Supply Mail Order Pharmacy 1
80.01-10 Direct Supply Retail Pharmacy 2
80.01-11 Dispensing Practitioner 2
80.01-12 Drug Utilization Review (DUR) 2
80.01-13 Drug Utilization Review Committee (DUR Committee) 2
80.01-14 Formulary 2
80.01-15 Generic Drugs 2
80.01-16 Maine Drugs for the Elderly Program (DEL) 2
80.01-17 Legend Drug 2
80.01-18 Mail Order Pharmacy 2
80.01-19 Maine Maximum Allowable Cost (MMAC) 3
80.01-20 Maintenance Drugs 3
80.01-21 Maximum Allowable Cost (MAC) 3
80.01-22 Medical Food 3
80.01-23 Medi-Span 3
80.01-24 Metropolitan Statistical Area (MSA) 3
80.01-2~~4~~5 National Drug Code (NDC) 3
80.01-2~~5~~6 New Drugs 3
80.01-2~~6~~7 Non-Preferred Drugs 3
80.01-2~~7~~8 OBRA 90 3
80.01-29 Over-ride 3
80.01-3~~028~~ Over-The-Counter Drug (OTC) 3
80.01-3~~129~~ Pharmacy Provider 4
80.01-3~~20~~ Preferred Drugs 4
80.01-3~~31~~ Preferred Drug List 4
80.01-3~~42~~ Retail Pharmacy 4
80.01-3~~53~~ Specialty Drug 4
80.01-3~~64~~ State Drug File 4
80.01-3~~75~~ Therapeutic Category 4
80.01-3~~86~~ Usual and Customary Charge 4

80.02 ELIGIBILITY FOR CARE 4

80.03 DURATION OF CARE 5

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

TABLE OF CONTENTS

PAGE

80.04 FORMULARY COMMITTEE 5

80.04-1 Purpose 5
80.04-2 Membership 5
80.04-3 Meetings 5
80.04-4 Approval of New Drugs 6
80.04-5 Formulary Policy and Procedures 6

80.05 COVERED SERVICES 8

80.05-1 Drug Benefits 8
80.05-2 Compound Prescriptions 9
80.05-3 Drugs Covered for Certain Conditions/Procedures Only 9
80.05-4 Drugs Obtained Through The Department's DSDL Mail Order Pharmacies 10

80.06 NON-COVERED SERVICES 11

80.07 POLICIES AND PROCEDURES 12

80.07-1 Regulation of Pricing 12
80.07-2 Standards of Participation for Retail Pharmacies 13
80.07-3 Standards for Mail Order Pharmacies 13
80.07-4 Prior Authorization (PA) 14
80.07-5 Preferred Drug List (PDL) 16
80.07-6 Dispensing Practices 19
80.07-7 Refills 20
80.07-8 Pharmacist's Responsibility 21
80.07-9 Restriction and Narcotic Prescriber Plans 21
80.07-10 Surveillance and Utilization Review 21
80.07-11 Maine Retail Pharmacy Provider Incentive Payment 21

80.08 CO-PAYMENT 22

80.09 REIMBURSEMENT 23

80.10 BILLING INSTRUCTIONS 29

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.01 DEFINITIONS

80.01-1 Brand-Name Drug is defined as a single-source drug, a cross-licensed drug, or an innovator drug.

80.01-2 Caloric Supplements/Substitutes are over-the-counter products that contain fats, and/or proteins, and/or carbohydrates and are prescribed by a licensed provider for the express purpose of enhancing caloric intake to address an illness or condition, and which have a standard national drug code (NDC) number in the Medi-Span drug file database.

80.01-3 Compound Prescription is any product for which two or more ingredients are extemporaneously mixed in usually accepted therapeutic doses. This requires the pharmacist's skill in weighing, measuring, levigating, etc., at the time of dispensing. The allowable compounding fee applies to the preparation of an individual prescription. It does not apply to prescriptions dispensed from a previously prepared stock supply (i.e., premixing a special lotion or ointment in gallons or pounds).

80.01-4 Controlled Substances are drugs that come within the scope of the Controlled Substances Act and are divided into five schedules- I, II, III, IV, V.

80.01-5 Covered Drugs are drugs that are reimbursable pursuant to Section 80.05.

80.01-6 DESI means the Drug Efficacy Study Implementation Program of the Food and Drug Administration (FDA).

80.01-7 Direct Supply Mail Order Drug List (DSMODL) is a list of covered drugs established by the Department, consisting of certain maintenance drugs that the Department has determined may be obtained safely and efficiently through mail order from Department-approved Direct Supply Mail Order pharmacy providers. The Department will post and update the DSMODL on the designated website.

80.01-8 Direct Supply Mail Order pharmacy is a Department-approved mail order pharmacy that dispenses drugs on the Direct Supply Mail Order Drug List. A Direct Supply Mail Order pharmacy dispenses prescription medications by U.S. mail or private carrier. Direct Supply Mail Order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing, be licensed by the Maine Board of Pharmacy, be enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Direct Supply Mail Order pharmacies must dispense prescription medications from within the United States. Direct Supply Mail Order pharmacies must process claims through the State's electronic claims processing system to the standards required by the Department.

80.01-9 Direct Supply Retail Drug List (DSRDL) is a list of covered drugs established by the Department, consisting of certain maintenance drugs that may be obtained through the Department's Direct Supply Retail pharmacy provider. The Department will post and update the DSRDL on the Department's designated web site.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.01 DEFINITIONS (cont.)

80.01-10 Direct Supply Retail pharmacy is a retail pharmacy approved by the Department to dispense drugs through the Direct Supply Retail Drug List

80.01-11 Dispensing Practitioner is a licensed practitioner who, within the scope of his or her license, prepares and dispenses medication, instructs patients to self-administer medication on a regular basis, and is located no less than fifteen miles from a licensed pharmacy.

80.01-12 Drug Utilization Review (DUR) means a process designed to ensure that prescriptions are appropriate, medically necessary and not likely to result in adverse medical results.

80.01-13 Drug Utilization Review Committee (DUR Committee) means an advisory committee to the Department of Human Services for the MaineCare program and other State prescription benefits administered by the Bureau of Medical Services, comprised of physicians and pharmacists who are licensed to prescribe or dispense drugs in Maine. The DUR Committee conducts drug utilization review for the Department.

80.01-14 Formulary is a list of medicines that includes all Legend (prescription) Drugs, to comply with OBRA 90 as amended, except those excluded by these regulations and those over-the-counter drugs listed in Section 80.05-1.

80.01-15 Generic drugs are drugs other than those defined as brand-name drugs.

80.01-16 Maine Drugs for the Elderly Benefit (DEL), formerly known as HMPD, provides low-cost prescription and limited over-the-counter drugs and medical supplies to certain elderly and disabled members pursuant to 22 M.R.S.A. Section 254. The DEL Benefit, which is not a MaineCare benefit, is further described in Chapter 104, Section 2.

80.01-17 Legend Drug is a drug bearing the statement "CAUTION: Federal Law Prohibits Dispensing Without A Prescription" or “Rx Only,” as allowed by the Food and Drug Administration.

80.01-18 Mail Order pharmacy is a pharmacy provider that dispenses prescription medications by U.S. mail or private carrier. Mail order pharmacies must have a NABP (National Association of Boards of Pharmacy) provider number uniquely identifying the provider as a mail order pharmacy for purposes of billing. Mail order pharmacies must be licensed by the Maine Board of Pharmacy, enrolled as Medicare and MaineCare providers, and be operating under contract with the Department. Mail order pharmacies must dispense prescription medications from within the United States. Mail order pharmacies must process claims through the State’s electronic claims processing system to the standards required by the Department.

80.01 DEFINITIONS (cont.)

80.01-19 Maine Maximum Allowable Cost (MMAC) is the maximum cost allowed by the Maine Department of Human Services for certain multiple source drugs.

80.01-20 Maintenance Drugs are drugs that are used to treat conditions that are usually chronic or long-term. Maintenance drugs include caloric supplements/substitutes, medical foods, and specialty drugs.

80.01-21 Maximum Allowable Cost (MAC) is the Federal Upper Limit (FUL) established by the federal government for certain prescription drugs. The MaineCare program reimbursement to a pharmacy may not exceed the MAC for any such drugs.

80.01-22 Medical Food is a product prescribed by a licensed provider for a member with special nutrient needs, in order to manage a disease or health condition, when the member is under the provider's on-going care. The label must clearly state that the product is intended to manage a specific medical disorder or condition. An example of a medical food is a food for use by persons with phenylketonuria, i.e., foods formulated to be free of the amino acid phenylalanine.

80.01-23 Medi-Span is a nationally recognized published drug database. The Department uses the designations in this database to create its State drug file to determine which drugs are brand-name (single-source, cross-licensed or innovator) and which drugs are generic (multiple-source) drugs for the purposes of calculating reimbursement.

80.01-24 Metropolitan Statistical Area (MSA) is a Federal Office of Management and Budget (OMB) designation of urban and rural communities. A MSA must include at least one city with 50,000 or more inhabitants, or a Census Bureau-defined urbanized area (of at least 50,000 inhabitants) and a total metropolitan population of at least 75,000 (in New England). Additional cities and towns are included in the MSA if they meet federally specified requirements of commuting to the central area and other selected requirements of metropolitan character (such as population density and percent urban). A MSA is also considered a labor market area.

80.01-2~~5~~4 National Drug Code (NDC) is a universal drug coding system for human drugs established by the Federal Food and Drug Administration (FDA). The FDA assigns each drug a unique identifier specifying the labeler/vendor, product, and package.

80.01-2~~6~~5 New Drugs are drugs that receive a New Drug Application (NDA) from the Food and Drug Administration after November 1, 1990.

80.01-2~~7~~6 Non-Preferred Drugs are covered drugs that are not preferred drugs.

80.01-2~~8~~7 OBRA 90 is the Omnibus Budget Reconciliation Act of 1990 as amended.

80.01-29 Over-ride is a situation where unusual circumstances warrant the Department to authorize a pharmacy to waive a standard condition or requirement for dispensing a medication in order to process a claim. One-time over-rides enabling a pharmacy to dispense a 4-day supply or less do not constitute continued benefits under MaineCare.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.01 DEFINITIONS (cont.)

80.01-3028 Over-The-Counter Drug (OTC) is a drug that can be purchased without a prescription.

80.01-3129 Pharmacy Provider is, for the purposes of determining the proper reimbursement charge, a corporation, association, partnership, or individual that either provides services pursuant to a provider agreement or is related by ownership or control to an entity that provides MaineCare services, and also accepts Medicare assignment. This definition of provider applies only to Section 80, Pharmacy Services, in the MaineCare Benefits Manual.

80.01-320 Preferred Drugs are covered drugs that have a lower net cost and/or advantages in clinical efficacy within a therapeutic category as determined by the Department after reviewing the recommendation of the Drug Utilization Review Committee.

80.01-331 Preferred Drug List (PDL) is a listing of covered drugs setting forth such information as their status as preferred or non-preferred, whether prior authorization is required, step order, and any other information as determined by the Department to be helpful to members, pharmacists, prescribers and other interested parties.

80.01-342 Retail Pharmacy is a pharmacy that possesses a valid outpatient pharmacy license issued by the Board of Pharmacy, accepts Medicare assignment, and which serves MaineCare members.

80.01-353 Specialty Drugs are covered drugs that ordinarily are not immediately available at local pharmacies due to their high cost, short shelf life, special handling requirements, or other factors. Specialty drugs are prescribed for a limited number of usually chronic conditions that generally affect a relatively small portion of the population.

80.01-364 State Drug File is the drug file database used by the Department for the purpose of managing the pharmacy benefit.

80.01-375 Therapeutic Category is a grouping of drugs by comparable therapeutic effect, as determined by the Department.

80.01-386 Usual & Customary Charge is the reimbursement amount the general public is requested to pay for the goods or services provided.

80.02 ELIGIBILITY FOR CARE

Individuals must meet the financial eligibility criteria as set forth in the MaineCare Eligibility Manual. Some members may have restrictions on the type and amount of services they are eligible to receive. It is the responsibility of the provider to verify eligibility and benefit level. The following members are eligible for some or all of the covered services set forth in this Section:

- MaineCare members who receive MaineCare full benefits and certain members who receive special benefits are eligible to receive pharmacy benefits as described in this Section.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.03 DURATION OF CARE

Each MaineCare member is eligible for as many covered services as are medically necessary within the limits of this Section. The Department reserves the right to request additional information to evaluate medical necessity.

80.04 FORMULARY COMMITTEE

80.04-1 Purpose

The purpose of the Formulary Committee, if initiated, will be to establish a formulary for the MaineCare program to identify which prescription and over-the-counter drugs are subject to coverage under the MaineCare program in compliance with OBRA 90 as amended (Title XIX, Section 1927). The statutory authority to establish a Formulary Committee is found at 22 M.R.S.A. 3174-M.

80.04-2 Membership

The Formulary Committee will be appointed by the Director of the Bureau of Medical Services. The Committee shall consist of nine members, including three actively practicing pharmacists and three actively practicing physicians.

At least one pharmacist shall be a clinical hospital pharmacist. At least one physician shall be a doctor who specializes in infectious diseases, one in primary care, and one in surgery. The pharmacists and physicians shall be MaineCare providers and shall serve for staggered three-year periods of time at the pleasure of the Director of the Bureau of Medical Services.

In addition to the members outlined above, the Director of the Bureau of Medical Services or the Director's designee, as well as the Pharmacy Unit Manager employed by the Bureau of Medical Services, and the Director of the Bureau of Health or the Director's designee shall serve on the Committee. In addition to the nine voting members outlined above, the Formulary Committee will have at least two non-voting consumer members appointed by the MaineCare Advisory Committee, who shall not be included when determining a two-thirds majority. The committee shall choose a chairperson from among the voting members. A secretary will be appointed by the Director of the Bureau of Medical Services.

80.04-3 Meetings

Meetings of the Drug Formulary Committee will be held at the discretion of the Director of the Bureau of Medical Services or the Committee Chairperson upon written petition of one-third of the Committee members.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.04 FORMULARY COMMITTEE (cont.)

80.04-4 Approval of New Drugs

Drugs will be added to the formulary, and will be deleted from the formulary, only upon a vote of two-thirds of the Formulary Committee members present, the procedure for which is described in Section 80.04-5. When a new drug does not meet the two-thirds vote for approval to be added to the formulary, requests for such drugs shall be reviewed on a Prior Authorization (PA) basis as outlined in Section 80.07-4.

80.04-5 Formulary Policy and Procedures

A. Drugs will be considered for addition to the formulary in one of four ways:

1. By the Formulary Committee, on the basis of evidence of sufficient requests for the drug through the PA process outlined in Section 80.07-4 to justify consideration for addition to the formulary.

   The Bureau of Medical Services may also request consideration of drugs based on the volume of inquiries received.

2. The Committee may initiate consideration of over-the-counter drugs, since such drugs are not generally approved through the PA process.

3. The Committee may also, through an on-going review of the formulary by therapeutic class, identify areas that are deficient or areas of possible deletion or restriction.

4. The drug manufacturer may initiate consideration of drugs for which there will be no fiscal impact as defined herein.

B. The steps to be followed for consideration by the Committee for the addition of drugs to the formulary are as follows:

1. The Department will prepare material for distribution to Committee members commenting on efficacy, therapeutic benefits, and current peer reviewed literature.

   The Committee will arrange for specialty providers, as appropriate, to comment on this written material. The Department shall classify the drug(s) under consideration into one of three categories, described below, which shall trigger a predetermined procedure. The Committee shall review that determination and after review of the available material, may change the determination by a two-thirds majority vote of those members present.

80.04 FORMULARY COMMITTEE (cont.)

Category A:

Therapeutic benefit and no projected fiscal impact or No therapeutic benefit and no projected fiscal impact.

Approval for drugs with no fiscal impact as defined herein shall be submitted to the next meeting of the Formulary Committee and shall be automatically recommended for addition to the formulary. No projected fiscal impact is defined as follows.

Reimbursement for the drug at the lowest adult daily dose for the primary indication will be compared to the average of the costs of the lowest adult daily dose for drugs within the same class, weighted by utilization for each drug within that class for the prior quarter. No consideration should be given to recommended course of therapy, improved, compliance, etc., for drugs in this category.

For combination drugs, the billed amount should be less than the combined prices of its components to have no fiscal impact.

Category B:

Therapeutic benefit and a projected fiscal impact.

Therapeutic benefit is defined as a clinically (not pharmacologically) more effective drug and/or a less toxic drug than alternative therapies currently on the formulary. A drug for which the sole advantage is convenience or compliance is not considered to have a therapeutic benefit.

Therapeutic benefit will be addressed by the clinician assigned the particular drug through his or her review with a final determination made by the Committee.

Drugs with an estimated fiscal impact shall normally be added to the formulary only in one of two ways:

a. a specific appropriation of funds from the Legislature with approval of the Governor; or

b. a deletion of other drugs from the formulary to maintain budget neutrality.

The therapeutic benefit of the drug being considered should be weighed against the therapeutic benefit of drugs already on the formulary. If the value of the drug under consideration is not thought to be great enough to justify an offsetting deletion and if no funds are appropriated for the addition, the drug shall be put on a pending list of drugs to be added to the formulary once funds become available.

80.04 FORMULARY COMMITTEE (cont.)

Category C:

No therapeutic benefit and a projected fiscal impact.

Drugs determined to be of no therapeutic benefit that have a projected fiscal impact shall not be added to the formulary. Such drugs would be available only through the PA process to the extent necessary for a specific individual.

2. At the conclusion of discussion of all drugs being considered at a meeting, the Committee members shall record their vote for each drug on a form to be supplied at each meeting. The Chairperson will tally the votes and announce the Committee's preliminary determination. Written documentation of the vote will be kept on file at the Bureau of Medical Services.

3. The Department shall promulgate as a rule any additions or deletions to the formulary. After any hearing or comment period has expired, the Committee shall review any comments and take a final vote on the addition or deletion of any drugs. Any preliminary or final determination by the Committee requires a two-thirds majority vote of the members present. Inclusion of a drug on the formulary will automatically include all conventional dosage forms of that drug, with the exception of transdermal systems, sustained release and injectable dosage forms, unless specifically approved by the Formulary Committee.

4. All drugs added to the formulary will be referred to the Drug Utilization Review Committee for monitoring.

80.05 COVERED SERVICES

80.05-1 Drug Benefits

Reimbursement is available for the following drugs when medically necessary.

A. Legend drugs. All legend drugs found on the MaineCare program State drug file, except those drugs set forth in Section 80.05-3, which must meet the requirements of prior authorization, and those drugs set forth in Section 80.05-4, which are covered for certain diagnoses only as set forth in that Section. In addition, those legend drugs described as a non-covered service in Section 80.06 are not reimbursable.

B. Over-the-Counter drugs. Some over-the-counter drugs and supplies are covered when filled pursuant to a prescription. Over-the-counter drugs will be eligible for reimbursement, by prescription only, if such coverage is efficacious, safe, has a lower net cost, the drug has an NDC, and coverage is recommended by the Drug Utilization Review Committee and approved by the Department. A list of

80.05 COVERED SERVICES (cont.)

covered over-the-counter drugs will be posted and updated on the Department's designated website.

80.05-2 Compound Prescriptions

Reimbursement may be made for a compound prescription when the Department determines that the compound prescription contains at least one ingredient that is a legend drug, present in a therapeutic quantity, and obtainable in effective strength only by prescription. A compound prescription, which contains a laxative, stool softener, vitamin, antacid or cough and cold preparation and is prescribed solely to circumvent these MaineCare reimbursement limitations, is not covered. Reimbursement for compound drugs must not include the cost of DESI (less than effective) drugs. The primary ingredient contained in a compound prescription must be covered under a rebate agreement with the MaineCare program and have a valid NDC in the State's drug file.

80.05-3 Drugs Covered for Certain Conditions/Procedures Only

Reimbursement for the following drugs will be made only for the conditions described and only when the prescriber has written the diagnosis on the prescription. For a member living in a nursing facility or an ICF-MR the diagnosis must only be noted in the member's chart.

A. Methamphetamine, methylphenidate, dexmethylphenidate, and dextroamphetamine for attention deficit disorders or narcolepsy only.

B. B-12 for documented pernicious anemia or megaloblastic anemia only.

C. Aspirin, buffered aspirin, enteric-coated aspirin and acetaminophen for arthritis or heart disease.

D. Multi-vitamins and vitamin E for cystic fibrosis.

E. The following oral drugs are covered for chronic renal failure, renal transplant and dialysis:

Aluminum Carbonate Gel, Aluminum Hydroxide, Bisacodyl, B vitamins with C, calcium products including calcium oyster shell, Calcitriol, Calcifediol, DHT (Dihydrotachysterol), Docusate w/Casanthranol, Ergocalciferol 50,000u, iron containing products, Magaldrate; multi-vitamins with 1mg. folic acid, phosphorous replacement products, Psyllium Hydrophilic Mucilloid, thiamin.

F. The following drugs are covered for members with quadriplegia and paraplegia:

Antacids, ascorbic acid, Bisacodyl, calcium oyster shell, Docusate w/Casanthranol, fleet enemas, glycerin suppositories, lubricating jelly, mineral oil, multivitamins, povidone iodine gel, Psyllium Hydrophilic Mucilloid, stress vitamins, and vitamin C & D.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.05 COVERED SERVICES (cont.)

G. Prescription, single dose laxatives are covered when necessary for conducting diagnostic tests in a non-hospital setting.

H. For members using nasogastric, gastrostomy or jejunostomy tubes, total enteral nutrition products are covered.

I. For members who are currently malnourished or at significant risk for malnourishment secondary to an underlying medical condition, specified nutritional support products are covered.

a. Currently malnourished: A Subjective Global Assessment (SGA) must be completed and submitted for risk assessment/documentation before prior authorization can be considered.

b. At significant risk for malnourishment secondary to an underlying medical condition. Documentation of medical condition must be submitted before prior authorization can be considered. A Subjective Global Assessment may be requested.

Prior to consideration for authorization, the member's prescriber must supply the following additional documentation in writing: A description of the attempts made to employ other oral measures to correct the risk/condition; supplement used; timeframe of use; reason for failure. Documentation that other oral measures are contraindicated and the reason why must also be submitted.

J. Single entity dietary vitamins in prescription strengths only when used for a documented vitamin deficiency or prophylaxis to prevent such deficiency.

80.05-4 Drugs Obtained Through the Department's DSDL Mail Order Pharmacies

Members are not required to obtain drugs through mail order. Members may voluntarily choose to obtain drugs on the Direct Supply Mail Order Drug List from DSMODL mail order pharmacies. There is no member co-payment for drugs on the Direct Supply Mail Order Drug List when obtained through the Department's DSMODL mail order pharmacies. The Department or DSMODL mail order pharmacies will provide members and providers with the DSMODL and instructions for submitting a prescription by mail order.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.05 COVERED SERVICES (cont.)

80.05-5 Drugs Obtained Through the Department's Direct Supply Retail Drug List Pharmacies (DSRDL)

DSRDL retail pharmacies may only dispense drugs on the Direct Supply Retail Drug List.

80.05-6 Drugs Obtained Through the Department's approved Mail Order Pharmacies

Members are not required to obtain drugs from mail order pharmacies. Members may voluntarily choose to obtain drugs from the Department's approved mail order pharmacies. Mail order pharmacies may only dispense 90-day supplies. All prior authorization requirements apply to drugs obtained through mail order pharmacies. There is no member co-payment for drugs obtained through the Department's mail order pharmacies. The Department or the mail order pharmacies will provide members and providers with instructions for submitting a prescription by mail order.

80.06 NON-COVERED SERVICES

MaineCare does not reimburse for the following drugs or products as drugs:

A. Anorexic, or certain weight loss drugs.

B. Vitamins and vitamin combinations except vitamins covered for dialysis and members with quadriplegia and paraplegia or when the criteria in Section 80.05-3(B) and Section 80.05-4(E) are met), and prenatal vitamins.

C. Hexachlorophene scrubs for nursing facility patients.

D. Products listed as part of the per diem rate of reimbursement in Chapter II, Section 67, Nursing Facility Services, or as defined in Section 50, ICF-MR Services, or as defined in Section 60, Medical Supplies and Durable Medical Equipment, of the MaineCare Benefits Manual or as defined in Attachment A or B of the Agreement between the Department and an assisted living facility.

E. Drugs discontinued or recalled by the manufacturers.

F. Less than Effective Drugs (DESI) as defined by the Food and Drug Administration.

G. Drugs prescribed for TB (these are normally available free of charge from the Bureau of Health's Tuberculosis program). MaineCare coverage is only available after referral from the Bureau of Health and MaineCare prior authorization.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.06 NON-COVERED SERVICES (cont.)

H. Over-the-counter drugs except drugs listed on the Department's designated website.

I. Any drug that is for experimental use or prescribed for indications other than those approved under OBRA 90 guidelines or have no Food and Drug Administration (FDA) sanctioned or approved indications.

J. Drugs not covered under OBRA 90 as amended.

K. Drugs prescribed primarily for cosmetic purposes, i.e., Retin-A when used for wrinkles, Rogaine for hair growth.

L. Drugs of manufacturers not participating in the federal Medicaid Rebate program pursuant to 42 USC §1396r-8, except certain over-the-counter drugs, enteral and parenteral products and instances where no clinically equivalent drug is available.

M. Fertility drugs.

N. Drugs prescribed or nutritional support products as part or all of a voluntary weight loss program.

O. Agents when used for the symptomatic treatment of cough and cold unless on the Preferred Drug List.

80.07 POLICIES AND PROCEDURES

80.07-1 Regulation of Pricing

Drugs added and deleted and price changes with regard to drugs that fall within the parameters of the Federal Upper Limits will be updated upon notification from the United States Government Centers for Medicare and Medicaid Services (CMS - formerly Health Care Financing Administration).

Price changes with regard to drugs that fall within the MMAC guidelines and all other MaineCare drug benefits will be updated according to periodic review by the Department of fluctuations in the average wholesale price list maintained by the Department of Human Services, Bureau of Medical Services under the guidelines of OBRA 90, as amended.

Designation of an effective date for all such changes will be determined together with allowance for mailing requirements in order to afford a minimum thirty-day notice to the provider.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.07 POLICIES AND PROCEDURES (cont.)

80.07-2 Standards of Participation for Retail Pharmacies

A pharmacy provider must be duly licensed or certified by the appropriate regulatory body in the state in which it is located, and must also be approved and accepting Medicare assignment.

An out-of-state provider may participate and receive payment for dispensed drugs only if the member has been injured or suffers a disease or illness while temporarily absent from Maine. MaineCare will only reimburse drugs dispensed by out-of-state providers on an emergency basis. Coverage of chronic or maintenance drugs is not considered an emergency. Exceptions to this requirement are 1) border providers (New Hampshire), as defined in Chapter I, that provide regular services to Maine members; or 2) those pharmacies that provide drugs for foster care children or other members who permanently reside in other states and are wards of the State of Maine.

A. A pharmacy provider will receive reimbursement only for drugs supplied by manufacturers who comply with the rebate requirements of the CMS in accordance with the Omnibus Budget Reconciliation Act of 1990. If a pharmacy provider does not have a drug available that is provided by a manufacturer/ labeler who complies with the rebate requirement of CMS in conformance with OBRA 90, the pharmacist must directly and individually inform the individual of other pharmacies that may carry the drug. Additionally, drugs that are otherwise covered by MaineCare but are provided from manufacturers/labelers not covered under the rebate agreement may be subject to prior authorization requirements upon thirty days written notice from the Bureau. (See 80.07-4 for prior authorization policy.)

B. Any pharmacist or dispensing practitioner, whether in state or out-of-state, who wishes to submit claims for payment must be an approved MaineCare provider. Providers must submit an application (MaineCare program Provider/Supplier Agreement) for approval by the Bureau of Medical Services, Provider File Unit. The Bureau will review the application and notify the submitting provider whether or not he or she is accepted as a provider and if accepted, the effective date. An application may be denied, terminated or not renewed for any of the grounds set forth in the MaineCare Benefits Manual, Chapter I.

A signed agreement must be on file before any reimbursement for any item or service will be made.

80.07-3 Standards for Mail Order Pharmacies and Direct Supply Mail Order Pharmacies

Mail order pharmacies and Direct Supply mail order pharmacies must be appropriately licensed by the Maine Board of Pharmacy and by the appropriate licensing authority in the state in which they are located. Mail order pharmacies and Direct Supply mail order pharmacies must satisfy all MaineCare provider enrollment requirements including, but not limited to, standards for quality of care and prior authorization requirements as established by the Department, accept Medicare assignment, and operate under contract with the Department. Mail order pharmacies and Direct Supply

80.07 POLICIES AND PROCEDURES (cont.)

mail order pharmacies must dispense MaineCare prescription medications from within the United States.

80.07-4 Prior Authorization (PA)

A. Determining Which Drugs May Be Subject to Prior Authorization

The Department may require prior authorization for certain drugs as set forth in this Section. In all instances, MaineCare members will be assured access to all medically necessary outpatient drugs.

In determining when prior authorization will be required, the Department will consider the recommendations of the DUR Committee. The Department will provide notice of DUR meetings in newspapers, through legislative notice procedures, and to the Maine Medical Association.

Those portions of the meetings that do not involve confidential or protected information, including, to the extent possible, the process of decision making, shall be open to the public.

The determination to impose prior authorization will be based on the efficacy, safety, and net cost of any given drug and of the other drugs within the therapeutic category. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, the DRUGDEX Information System, and American Medical Association Drug Evaluations. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 80.09, as adjusted by any manufacturer rebates and/or supplemental rebates to be paid to the Department for that drug. The Department may not consider net cost when imposing prior authorization unless it determines that the drug to be subject to prior authorization has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose.

The Department will provide prescribers with the list of drugs subject to prior authorization by posting and updating it on the designated website.

The Department may require prior authorization of any generic drug that has a net cost that is greater than the net cost of its brand-name version.

The Department, in consultation with the DUR Committee, may determine that the prior authorization requirement may be waived on a case-by-case basis for members who are established on a drug that otherwise might be subject to prior authorization.

80.07 POLICIES AND PROCEDURES (cont.)

B Process for Seeking Prior Authorization

When the Department requires prior authorization, the member's prescriber must complete a form in writing and submit it and any required attachments, documenting the medical necessity of the prescribed drug. The Department may seek information, such as documentation of other measures that have been attempted to correct the risk/condition, the timeframe in which those other measures were attempted, and the reason for failure. The prescriber is also required to submit documentation that other drugs in the same therapeutic category are contraindicated.

The Department will notify prescribers of the drugs that are subject to prior authorization and will provide them with forms for requesting authorization setting forth the information needed to approve a request. The forms will also be available on a website designated by the Department.

The requesting prescriber must complete the form applicable to the drug for which prior authorization is sought. The prescriber must send the completed form to the Department or its designee, as instructed by the Department, by mail, fax or by hand delivery, in compliance with the Health Insurance Portability and Accountability Act (HIPAA) standards.

During regular business days, the Department or its designee will respond to a completed request for prior authorization by fax, telephone or other telecommunications device within 24 hours of receipt.

In an emergency situation, including weekends, holidays, or any other time that the Department or its designee is not able to respond to a completed prior authorization request within 24 hours of receipt, the pharmacy provider is authorized to provide a one-time 96-hour supply of any prescribed drug that is a covered drug. The Department or its designee shall respond to a completed request under this subpart on the next regular business day. The provision of a 96-hour supply under this subpart does not relieve the prescriber of the obligation to complete and submit the prior authorization request form.

In the event that a prescriber fails to submit a completed form for a drug requiring prior authorization, the Department or its designee may authorize the pharmacy provider to dispense a one-time 34-day supply of the prescribed drug. The authorization of a 34-day supply under this provision does not relieve the prescriber of the obligation to complete and submit the prior authorization request form. If the prescriber has still failed to submit a completed prior authorization

80.07 POLICIES AND PROCEDURES (cont.)

request by the end of the additional 34-day period, the Department will consider any refills of that prescription on a case-by-case basis.

Prior authorization is effective for twelve (12) months unless otherwise specified by the Department.

C. Temporary Prior Authorization Requirements:

Drugs that have not been reviewed by the DUR Committee may be subject to temporary prior authorization by the Department under the following circumstances:

1. The Department may impose temporary prior authorization requirements on drugs that have been added to the State drug file since the last meeting of the DUR Committee if the Department determines that those drugs present substantial concerns regarding efficacy, safety or cost; and

2. The Department may impose temporary prior authorization requirements on drugs that are already covered by MaineCare if, since the last meeting of the DUR Committee, the Department has received new or additional information raising a substantial concern regarding efficacy, safety or cost.

Temporary prior authorization requirements imposed pursuant to this subsection shall conform to current DUR Committee prior authorization guidelines described above, and shall be effective immediately. Drugs subject to temporary prior authorization shall be reviewed at the next meeting of the DUR Committee.

80.07-5 Preferred Drug List

A. General

In order to facilitate appropriate utilization, the Department will establish a list of covered drugs, ordered by therapeutic category. This listing will be known as the Preferred Drug List or PDL. Within each therapeutic category, the Department may designate some or all drugs as preferred on the basis of efficacy, safety, and net cost. The Department's determination of a drug's efficacy and safety shall be consistent with the standards set forth in (1) the peer-reviewed literature, and (2) the following compendia: the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information, and the DRUGDEX Information System. The Department's determination of a drug's net cost shall consider the pharmacy reimbursement amount as set forth at Section 80.09, as adjusted by any manufacturer rebates and/or supplemental rebates to be paid to the Department for that drug. The Department may

80.07 POLICIES AND PROCEDURES (cont.)

not consider net cost unless it determines that the drug has no significant clinical or safety advantages over one or more alternative drugs, when used for a given purpose.

In addition to the preferred/non-preferred designation, the PDL may include information such as generic name, strength/unit, National Drug Code identification number, and brand name.

All covered drugs, whether preferred or non-preferred, are available to any eligible member for whom those drugs are medically necessary. Some drugs must have their medical necessity confirmed for a given member through the prior authorization process before the Department will provide reimbursement.

B. Step Order

In addition to the preferred/non-preferred designations, the Department may assign some drugs on the PDL a further designation of preference within a therapeutic category. This further designation will be known as step order.

The step order is a means of reducing the need to obtain prior authorization. When a member has been prescribed all drugs at a higher step(s) within a therapeutic category, the drug at the next lower step will automatically be reimbursed for that member without requiring prior authorization. Only drugs prescribed to the member since enrollment and reflected in the Department's automated pharmacy management information Point of Purchase System will be considered in applying the step order.

C. Five Brand-Name Limit

The Department may require prior authorization for brand-name prescriptions when certain members over the age of 21 obtain more than five brand-name prescriptions per month. The Department may exclude from this PA requirements drugs for the treatment of cancer, HIV, hemophilia, or other conditions. The Department may require PA for the sixth and subsequent brand-name prescriptions in that one-month period. This five brand-name may apply to:

1) Members residing in certain supervised settings, specifically nursing facilities, medical and remedial private non-medical institutions, ICFs-MR, adult family care homes, and assisted living facilities; and

2) Members who are eligible for MaineCare as part of the Non-Categorical Waiver as described in the MaineCare Eligibility Manual, Chapter 11000, when and if approved by the Centers for Medicare and Medicaid Services (CMS). Members will be given 15 days notice of this change.

80.07 POLICIES AND PROCEDURES (cont.)

D. Other Limitations

1. Drug Benefit Management

The Department may provide drug benefit management to certain high-cost and/or high utilizing members of the MaineCare pharmacy benefit. The Department may identify these members by reviewing any or all of the following factors: drug costs within the top 10% of the aggregate prescription drugs costs, utilization within the top 10% of specific drug categories, or high costs or utilization within specific drug categories where more cost-effective drug therapies could be utilized while maintaining or improving health outcomes. The Department may provide drug benefit management intervention for these members and/or prescribers by providing education and case management.

2. Intensive Benefits Management

The Department may provide intensive benefits management for members for whom drug benefit management does not result in the implementation of targeted recommendations. As part of the ongoing drug utilization review process, members whose drug profiles are of sufficient complexity, or who receive prescriptions from multiple prescribers, or who have persistent early refills, or whose prescribers have demonstrated frequent disregard for Departmental policies, may be identified for participation in intensive benefits management. Intensive benefits management may require long-term case management for members, enhance coordination of care among providers, address inappropriate prescribing behavior, and promote cost-effective pharmaceutical care.

Intervention also may require prescriber and/or pharmacy lock-in, prior authorization of all drugs, assignment of prescribers to peer review, and enrollment of members in disease management services or intensive medical management. The Department also may require member participation in the Restriction and Narcotic Prescriber Plans, as described in Chapter IV, Section 1 of the MaineCare Benefits Manual.

E~~C~~. Notification

The Department will post the PDL and any changes on the Department's designated website. The Department will also provide quarterly notification of the drugs selected for placement on the PDL, and any other changes in the PDL.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.07 POLICIES AND PROCEDURES (cont.)

80.07-6 Dispensing Practices

Compliance with the following dispensing policies is required:

A. Dispensing practices must be in accordance with the best medical, pharmaceutical and economical practice.

B. Generic drugs as rated A in the current edition of the FDA Orange Book must be dispensed in accordance with State law, if available at a lower cost than the brand name product, unless a prior authorization for medical necessity for the brand name drug is submitted to and approved by the Department or the generic drug has been designated by the Department as requiring prior authorization. Prescribers and providers will be informed of generic drugs that have been designated as requiring prior authorization. Those drugs will be listed and updated on the Department's designated website.

C. Single source, brand multisource or co-licensed drugs must be dispensed in quantities not to exceed a 34-day supply, unless dispensed by the DSMODL or mail order pharmacy, which allows a 90-day supply only. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy, up to 90 days. Pharmacists will not be reimbursed for split prescriptions unless necessary to meet MaineCare policy, including but not limited to dispensing a 34-day supply. Also see Section 80.09. Where unit of use packaging prevents the pharmacist from measuring a 34-day supply (e.g., ointments, eyedrops, insulin and inhalers) prescriptions shall be dispensed in a size consistent with a 34-day supply.

D. Payment for medications dispensed in quantities in lesser or greater amounts than therapeutically reasonable may be withheld pending contact with the prescriber to determine justification for the amount.

E. All prenatal vitamins must be dispensed in quantities for up to a 100-day supply with no more than three refills.

F. Aspirin and acetaminophen must be dispensed in quantities of 100, 250, 500 or 1000 only.

G. Upon dispensing the prescription in person, the pharmacy provider must obtain a signature verifying receipt from the member or person picking up the prescription.

H. MaineCare will allow a one-time 4-day over-ride per calendar year per member under the following conditions: vacation, lost or stolen medication, change of dosage, change of residential location, or emergency supply for long-term care facilities. The Department will review requests for other over-rides on a case-by-case basis.

80.07 POLICIES AND PROCEDURES (cont.)

A pharmacy affiliated through common ownership or control with a hospital, boarding home, ICF-MR, private non-medical institution, assisted living facility and/or nursing home is allowed to dispense covered MaineCare prescription drugs to MaineCare members in that facility. Providers must report these affiliations to the BMS Provider File Unit and the Pharmacy Director. A registered pharmacist must dispense the drugs according to dispensing regulations. Drugs are to be billed in a manner consistent with the Department's billing guidelines and drug claim processing system (see Section 80.09) without a professional dispensing fee.

Practitioners who have been authorized to dispense drugs for MaineCare members shall not receive a dispensing fee, but will be allowed to charge the co-pay amount in addition to the acquisition cost of drugs dispensed. Records of all such dispensing must be available for review and audit.

A pharmacy provider must maintain the original or electronic copy of all prescriptions for which payment from the MaineCare program is requested. The original prescription shall be either a hard copy generated by a computer, written by the prescriber, or reduced to writing when received by the pharmacist by telephone. Information required by the Maine State Board of Pharmacy shall be recorded on each prescription and must include name of member, name of drug, quantity ordered, directions, name of prescriber, date written and initials of pharmacist filling prescription. A record of each refill must be kept on the prescription or on the profile or be available on a computer.

80.07-7 Refills

Reimbursement for refills will be made only if the following conditions are met:

A. The prescription authorizes refills.

B. No more than one year has passed since the date of the original issue. Reimbursement for a drug later than one year from the date of original issue requires a new prescription, subject to the limitations described in subsection 80.07-6, Dispensing Practices.

C. Reimbursement will be made for refills dispensed in no less than a 30-day supply for conditions except when the prescriber specifically directs otherwise. Mail order pharmacies may only dispense 90-day supplies.

D. Single source, brand multisource or co-licensed drugs must be dispensed in quantities not to exceed a 34-day supply, except for mail order pharmacies, which may only dispense 90-day supplies. If a member will suffer undue hardship from the requirement that prescriptions must be refilled every 34 days, the provider may submit a miscellaneous prior authorization form requesting authorization to dispense a 90-day supply. FDA A-rated generic drugs must be dispensed in quantities sufficient to effect optimum economy, not to exceed 90 days. Pharmacy providers will not be reimbursed for split prescriptions. See Section 80.07-6(C).

80.07 POLICIES AND PROCEDURES (cont.)

E. Early refills in excess of an 80% threshold, except for Oxycontin, must be authorized on a case-by-case basis through the Department or its designee.

F. Refills shall be mailed to the member upon request, where such mailing is the policy of the pharmacy provider with respect to the general public.

80.07-8 Pharmacist's Responsibility

The Department supports generally accepted professional judgments made by pharmacists, including the right to refuse to dispense any prescription that appears to be improperly executed or unsafe, based on the pharmacist's professional judgment. The Department expects that any pharmacist who suspects that a member may be inappropriately using a drug will report the member to the Pharmacy Unit or Surveillance and Utilization Review Unit, Bureau of Medical Services, 11 State House Station, Augusta, Maine 04333-0011.

80.07-9 Restriction and Narcotic Prescriber Plans

Some members may be enrolled in the Restriction and Narcotic Prescriber Plans. See Chapter IV, Section 1, of MaineCare Benefits Manual for more details.

80.07-10 Surveillance and Utilization Review

Surveillance and Utilization review requirements are delineated in Chapter I of the MaineCare Benefits Manual.

80.07-11 Maine Retail Pharmacy Provider Incentive Payment

The Maine Retail Pharmacy Provider Incentive Payment will reward pharmacies who provide quality pharmacy services to MaineCare members in rural areas. Retail pharmacies located in rural areas will be eligible for this payment. The Department will define rural retail pharmacies as those pharmacies not located in a MSA, as defined in Section 80.01. The distance of a pharmacy from another pharmacy is considered in determining the distribution of incentive payments.

The Department will calculate the incentive payment by creating a percentile score based on criteria described below. Each pharmacy's practices will be compared to other pharmacies and then given an overall percentile ranking. Eligible pharmacies ranking above the twentieth percentile will receive a monetary share of their pool within that percentile ranking, with the higher the percentile ranking, the higher the monetary share received. The twentieth percentile and below will not receive an incentive payment. The Department will calculate the incentive payment on a quarterly basis and send payments following the end of the quarter. The following describes factors considered to calculate the incentive:

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.07 POLICIES AND PROCEDURES (cont.)

A. Access for MaineCare Members Measured by Percentage of Unduplicated MaineCare Members Served (50%)

B. Rural Pharmacies Located At Least 10 miles from another pharmacy (10%)

C. Generic Drug Utilization Rate (5%)

D. PDL compliance (10%)

E. Ratios of PA's submitted to Claims Paid (5%)

F. Ratio of Early Refills and Emergency Claims Paid to Claims Paid (10%)

G. Other Third Party Payor Coverage Dollars Collected (5%)

H. Expanded Access for Members in Rural Areas (5%)

1. Delivery to members, either by mail or in person

2. Expanded hours

80.08 CO-PAYMENT

A co-payment is to be charged by the pharmacy to each MaineCare member for each prescription filled or refilled, with the exception of prescriptions filled by the Department's mail order pharmacies and DSMODL mail order pharmacies. Members shall not pay a co-payment for drugs obtained from the Department's mail order and DSMODL mail order pharmacies. Co-payment dispute resolution procedures are described in Chapter I of the MaineCare Benefits Manual. No pharmacy may discount the co-payment for promotional purposes.

A. Pharmacy Benefits Provided By Retail and DSRDL Pharmacies:

1. The amount of the co-payment shall be $2.50 per prescription, not to exceed $25 per member per month.

2. The pharmacy shall not deny pharmacy services to a MaineCare member on account of the member's inability to pay a co-payment. Providers must rely upon the member's representation that he or she does not have the cash available to pay the co-payment. However, the individual's inability to pay does not eliminate his or her liability for the co-payment.

3. If a member is dispensed a drug in a quantity specifically intended by the prescriber or pharmacist to last less than one month for the member's health and welfare, only one co-payment for that drug that month is required.

4. Co-payment exemptions are described in Chapter I of the MaineCare Benefits Manual.

80.08 CO-PAYMENT (cont.)

B. Pharmacy Benefits Provided By Department-approved Mail Order and DSDL Mail Order Pharmacies

Members shall have no co-payment for drugs dispensed through Department-approved mail order pharmacies and Direct Supply Drug List mail order pharmacies.

C. Benefit for People Living With HIV/AIDS

Co-payment policies for members receiving the Benefit for People Living with HIV/AIDS can be found in the MaineCare Benefits Manual, Chapter X, Section 1.

80.09 REIMBURSEMENT

80.09-1. Reimbursement Rates

MaineCare reimbursement for drugs covered under this Section will only be made for drugs of any manufacturer that has entered into and complies with a rebate agreement, except as noted in Section 80.09, and specific reporting requirements as defined by Title XIX of the Social Security Act Section 1927 described in OBRA 90 as amended.

A. Reimbursement for Retail Pharmacies:

1. Generic Drugs

The reimbursement rate for covered generic drugs shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus 13% plus $3.35 professional fee except as otherwise noted below, or

c. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $3.35 professional fee except as otherwise noted below.

2. Brand-name Drugs

The reimbursement rate for covered brand-name drugs shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus 15% plus $3.35 professional fee except as otherwise noted below, or

80.09 REIMBURSEMENT (cont.)

c. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $3.35 professional fee except as otherwise noted below.

B. Reimbursement for Drugs on the Direct Supply Drug List:

1. Direct Supply Retail Drug List (DSRDL) Providers

The reimbursement rate for covered drugs that are on the ply DSRDL and dispensed by retail providers shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus 17% plus $3.35 professional fee except as otherwise noted below, or

c. The Federal Upper Limit or the Maine maximum allowable cost plus $3.35 professional fee except as otherwise noted below.

2. Direct Supply Mail Order Drug List (DSMODL) Providers

a. Generic Drugs

The reimbursement rate for generic drugs obtained through Direct Supply Mail Order Drug List pharmacies shall be the lowest of the following:

i. The usual and customary charge; or

ii. The Average Wholesale Price minus 17% plus $3.35 professional fee except as otherwise noted below, or

iii. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $3.35 professional fee except as otherwise noted below.

b. Brand Name Drugs

The reimbursement rate for brand name drugs obtained through Direct Supply Mail Order Drug List pharmacies shall be the lowest of the following:

i. The usual and customary charge; or

80.09 REIMBURSEMENT (cont.)

ii. The Average Wholesale Price minus 17% plus $3.35 professional fee except as otherwise noted below, or

iii. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $3.35 professional fee except as otherwise noted below.

C. Reimbursement for Drugs Obtained Through Mail Order Pharmacies:

1. Generic Drugs

The reimbursement rate for covered generic drugs obtained through mail order pharmacies shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus 60% plus $1.00 professional fee except as otherwise noted below, or

c. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $1.00 professional fee except as otherwise noted below.

2. Brand Name Drugs

The reimbursement rate for covered brand name drugs obtained through mail order pharmacies shall be the lowest of the following:

a. The usual and customary charge; or

b. The Average Wholesale Price minus 20% plus $1.00 professional fee except as otherwise noted below, or

c. The Federal Upper Limit (FUL) or the Maine maximum allowable cost plus $1.00 professional fee except as otherwise noted below.

D. The Department's reimbursement rate will be reduced by any applicable member co-payment.

E. In accordance with Chapter I, of the MaineCare Benefits Manual, it is the responsibility of the provider to seek payment from every other source. It is the responsibility of the provider to verify a member's eligibility for

80.09 REIMBURSEMENT (Cont.)

MaineCare prior to providing services by requesting the individual to present his or her MaineCare ID card on each occasion that a service is provided and verifying this information as described in Chapter I of the MBM.

F~~D~~. If the provider is aware that a member's eligibility is due to expire within one month of the date of service, reimbursement will only be made for up to a one month's supply.

G. Maine Maximum Allowable Cost (MMAC). The establishment of a MMAC is subject, but not limited, to the following considerations:

1. Multiple manufacturers;
2. Broad wholesale price span;
3. Availability of drugs to retailers at the selected cost;
4. High volume of MaineCare member utilization;
5. Bioequivalence or interchangeability.

The Department will periodically notify pharmacies of updates to the list of drugs affected by FUL or MMAC pricing. This information will also be available on the BMS website.

H. Reimbursement for Drugs More Expensive Than MAC or MMAC Allowances

A prescriber who requests a drug more expensive than an equivalent MAC or MMAC limited generic drug must get prior authorization for the requested product before reimbursement will be permitted. Prescribers and providers will be notified of the drugs requiring prior authorization and this list, and any updates, will be posted on the Department's designated website.

I. Reimbursement for Compounded Drugs For Retail Pharmacies

Reimbursement for these drugs is determined by subtracting the co-payment described in Section 80.08, from the sum of the professional fee and the ingredient cost.

1. Professional fees for compound drugs are as follows:

a. Submitted by paper claim form:

(i) $3.35 for an amount dispensed from a stock supply, or for solutions or lotions involving no weighing.

80.09 REIMBURSEMENT (Cont.)

(ii) $5.35 for compounding handmade suppositories, powder papers, capsules and tablet triturates and for mixing home TPN hyperalimentation.

(iii) $4.35 for compounding ointments and for solutions or lotions involving weighing one or more ingredients and mixing home intravenous (IV) solutions.

(iv) $12.50 for filling insulin syringes per 14-day supply.

(v) The ingredient cost is the sum of the cost of the defined ingredients contained in the compound drug. For any ingredients that cost twenty-five cents or less, twenty-five cents is the allowed charge. Ingredients that are identified as DESI (less than effective) may not be included in the reimbursement for the compound drug.

b. Accepted electronically:

The Department will notify providers of changes in the electronic claims system process that will allow electronic processing of reimbursement for compound drugs.

J. Returned Reusable Drugs for Retail Pharmacies

All drugs dispensed to members in nursing facilities, ICFs-MR, and medical and remedial private non-medical institutions shall be dispensed in 34-day supplies except for Schedule II narcotics not used for maintenance therapy. Schedule II items may be dispensed in less than a 34-day supply if therapeutically and financially reasonable or to comply with the facility's stop order policies. Drugs in ointment form shall normally be dispensed in the largest size available.

1. Nursing facilities, ICFs-MR, and medical and remedial private non-medical institutions must identify discontinued reusable drugs and return them at the end of each month. All full or partial unit dose or modified unit dose drugs shall be returned to the pharmacy for credit except the following:

a. Liquids and ointments, unless sealed packages are unopened,

b. All controlled substances,

c. Inhalers, and

80.09 REIMBURSEMENT (Cont.)

d. Outdated or expired drugs.

According to State and Federal regulations, medication not returned to a pharmacy for credit must be destroyed in the facility by authorized staff.

2. Instructions for Return

a. Return Instructions for Facilities

Facilities will complete and submit before the 15th of each month a Pharmaceutical Control Sheet (MCMA- 45) for the previous month's returned reusable drugs for each pharmacy. Facilities must complete columns 1 through 6 on the MCMA-45, which includes, but is not limited to, provider information, prescription number and date filled, number of units, MaineCare member ID# and last name. The completed form must be signed and dated.

Facilities must return the forms and distribute copies of the completed form. Facilities must send green sheets with listed medication to the servicing pharmacy. Facilities must retain the blue sheet for facility files and return the original white copy to:

Third Party Liability
Attn: Returned Reusable Drug Unit
Bureau of Medical Services
11 State House Station
Augusta, Maine 04333-0011

b. Return Instructions For Pharmacies

Pharmacies must review MCMA-45 forms and drugs received from facilities for accurate accounting of returned drugs, and notify the Department of any discrepancies. Pharmacies must review the Department's claims reports (Rx Flagged for Reversal Report), and document disputes on the MCMA-45, column 7. If there is a dispute, the MCMA-45 form must be signed, dated, and returned to the Department within 15 calendar days from the date of the Department's reversal report. If there is no response from the pharmacy within 15 days, the Department will initiate claims reversals. For any returned reusable drug where the quantity reversed is equal to the original quantity dispensed, the pharmacy will be reimbursed $3.35.

SECTION 80 **PHARMACY SERVICES** Established 4/1/79

80.10 BILLING INSTRUCTIONS

A. Billing using paper claims must be accomplished in accordance with the Department's billing requirements, "Billing Instructions for Pharmacy Services."

B. Electronic billing must be accomplished in accordance with the Department’s billing requirements as described in the Electronic Media Claims rider to the Provider/Supplier Agreement.

C. Mail order pharmacies must comply with the Department’s billing requirements and submit claims through the Department’s claims system.